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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,144	07/13/2005	Juan Ramella	P70596US0	9818

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EXAMINER
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WIEST, PHILIP R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,144	<b>Applicant(s)</b> RAMELLA, JUAN	
	<b>Examiner</b> Phil Wiest	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/18/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to a bicompartiment bag, classified in class 604, subclass 403.
  - II. Claims 12-15, drawn to process for manufacturing a bicompartiment bag, classified in class 156, subclass 73.5.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the manufacturing method of Group II does not disclose all the specifics of the bushing of Group I. The method of Group II can be used to manufacture a structurally distinct bag, such as one wherein the inlet and outlet feed into the same compartment. Furthermore, the bag of Group I can be manufactured using a materially distinct process, such as using an O-ring to seal the bushing to the bag.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Harvey Jacobson on November 2, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Claim Objections***

Claims 4 and 10 are objected to because of the following informalities:

6. Claim 4 recites the limitation "said powdered solute" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. "Powdered solute" is not disclosed in Claim 2, which Claim 4 depends from. For the purpose of examination, Examiner assumes that Claim 4 depends from Claim 3.

7. Claim 10 recites the limitation "the powder solute" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. "Powder solute" is not disclosed in Claim 1, which Claim 10 depends from. For the purpose of examination, Examiner assumes that Claim 10 depends from Claim 3.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1, 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochat (US 5,269,924) in view of Macacasco et al. (US 5,573,527).

10. With respect to Claims 1 and 2 Rochat discloses a blood collecting and filtering apparatus 10 comprising two outer sheets and a third inner, flexible, screen-like sheet 12, which divides the bag into a first chamber 13 and second 14 chamber (see Figure 1), and a circular bushing 21 which is in communication with a first opening 15 of the bushing 21 to enable connection of the first chamber to a solvent line and a second opening 16 of the bushing 21 to enable exit of solution from the second chamber (see arrows on Figure 1). Rochat further discloses that the entire outer wall of the bag is

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watertight (Column 2, Lines 47-63). Rochat, however, does not disclose that the bushing is affixed on the side wall of the bag via a first bore in the outer sheet and a second bore in the inner sheet. Macabasco et al. disclose a medical bag comprising a bushing 114 built directly into the side of the bag 102. It would have been obvious to one skilled in the art at the time of invention to modify the blood collecting and filtering apparatus with the bushing location of Macabasco et al. in order to remove filtered fluid from a different location on the bag. Regarding Claim 2, Macabasco and Rochat both disclose bushings which are annular on the plane which projects toward the bag. See MPEP 2144.04.

11. With respect to Claim 10, Rochat discloses that the inner, screen-like sheet comprised a mesh filter 12 with openings between 100 and 1000 microns that is capable of retaining a powder solute (Column 2, Lines 40-47).

12. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochat in view of Macacasco et al., further in view of Mathieu (US 5,616,305).

13. With respect to Claims 3 and 4, Rochat and Macabasco et al. disclose the blood bag of Claim 1 (see above rejection). Rochat and Macabasco et al., however, do not disclose that the first chamber is at least partially filled with a powdered solute. Mathieu discloses a hemodialysis packaging unit comprising a layer of sodium bicarbonate powder 74 (Column 9, Lines 47-55). It would have been obvious to one skilled in the art at the time of invention to modify the blood bag system of Rochat and Macabasco et al. with the layer of sodium bicarbonate of Mathieu in order to allow for dialysis treatment of the blood. Furthermore, in the blood bag system disclosed by Rochat, it is inherent that

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the layer of sodium bicarbonate would be located in the first chamber 13, before the filtering layer 18, in order to prevent particles from mixing into the blood.

***Allowable Subject Matter***

14. Claims 5-9 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art teaches blood bag of Claim 1, but does not teach the layer attached to the second chamber and made from a woven or injected material, the bushing with a radial tube, the communication between sections of the bushing, the thin sheet with strength lines in a cross-shaped configuration, or the thread means for attaching the bag to the bushing.

***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Laffay et al. (FR 2,766,797)

Atad et al. (US 6,135,989)

Verkaart et al. (US 6,325,422)

Andreas (US 4,270,533)

Eisele (US 1,546,016)

Lynn et al. (6,745,902)

Bark et al. (US 5,772,644)

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235.

The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW  
11/8/2006

TATYANA ZALUKAEVA  
SUPERVISORY EXAMINER





